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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,144	06/08/2001	David Hung	05284.00092	6700

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BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,144

Applicant(s)

HUNG ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' election without traverse of Group III, claims 1 and 6-10, drawn to a composition for being applied to a breast nipple in preparation comprising various combinations comprising at least two of the active agents set forth in claims 1 and 6-10 and the election of species of a lactation-stimulating agent and a dye in Paper No. 13 is acknowledged. The claims have been examined only to the extent of applicants' election.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (U.S. Patent No. 5,248,615).

Keller et al. teach on column 5, lines 45-54, teach Applicants' lactation-stimulating agent, prolactin can be combined with dye particles in an aqueous solution.

Applicants' recitation in claim 1 of an intended use of application to a breast nipple in preparation for collecting ductal fluid not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition taught by Keller et

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al. Further, Applicants' claim 6 as presently drawn is the combination of the lactation-stimulating agent and a dye since the preamble of "system" in claim 6 is not considered in interpreting the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al. (U.S. Patent No. 5,509,586) in view of Keller et al. (U.S. Patent No. 5,248,615) and further in view of Tabar et al. of record..

Collier et al. teach the technique comprising the intramammary infusion by using a blunt-tip syringe comprising prolactin compound for enhancing the growth of mammary gland. (column 3, lines 45-60, column 22, lines 61-66). Collier et al. disclose that intraductal injection of lactogenic hormone (i.e. prolactin) induce lactation. (column 1, lines 51-61). Collier et al. do not teach the dye combined with prolactin.

Keller et al. teach on column 5, lines 45-54, teach a stable aqueous solution comprising prolactin and dye. (column 1, lines 31-33, column 5, lines 45-55). Keller et al. disclose that prolactin solutions are unstable. (column 2, lines 3-5).

Tabar et al. on page 36 middle column, teach that intraductal administration procedure is painful.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a system comprising blunt-tip syringe comprising prolactin and dye and anesthetic agent for intramammary infusion because unlike other prolactin solution, the aqueous prolactin solution comprising prolactin and dye is stable as taught by Keller et al. and because the intramammary infusion (intraductal administration) is painful as taught by Tabar et al. One would have been motivated to formulate a "system" comprising the stable aqueous solution with

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analgesic agent for the technique taught by Collier et al. to reduce pain during the procedure and also for the convenience for accessing the necessary agents in one "system".

Absent any evidence to the contrary, there would have been a reasonable expectation of success in using the compounds taught Keller et al. with anesthetic agent in the technique taught by Collier in one "system" to achieve expected stable and painless intramammary infusion.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. of record in view of Yates (U.S. Patent No. 6319510B1).

Keller et al. ~~teach~~ on column 5, lines 45-54, teach a stable aqueous solution comprising prolactin and dye. (column 1, lines 31-33, column 5, lines 45-55).

Yates teach ~~on~~ that gum pad can be used for the topical systemic delivery of a wide range of pharmaceutical agents including prolactin.

It would have been obvious to one of ordinary skill in the art to formulate a "system" comprising Keller et al.'s composition together with Yates pad because the gum pad can be used for the topical systemic delivery of prolactin. One would have been motivated to formulate Keller et al.'s composition together with Yates pad in a "system" to formulate topical systemic delivery of active agent prolactin. Absent any evidence to contrary, there would have been a reasonable expectation of success in combining the composition taught by Keller et al. with the pad taught by Yates to achieve expected benefit of topically delivery of active therapeutic agent, prolactin.

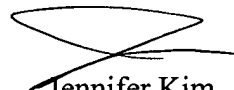
For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Jennifer Kim
Patent Examiner
Art Unit 1617

jmk
May 19, 2003